REMARKS

As a RCE is being filed herewith, this amendment and the previously filed IDS should be considered by the Examiner at this time.

Applicants have the following comments in response to the Final Rejection of January 11, 2006.

I. Claim Amendments – Reference to Disclosure

As explained in depth below, while Applicants respectfully traverse the rejections in the January 11, 2006 Final Rejection, in order to advance the prosecution of this application, independent Claims 1, 31, 68 and 85 have been amended to bring them into better conformance with the disclosure in the present application. Examples in support of such claimed methods are found throughout the specification of the present application, as discussed *infra*.

In the specification, Applicants teach that it is desirable to use a brief accumulation period following application of PDT agent during which such agent accumulates in diseased tissue. Following such accumulation period, the specification teaches that it is desirable to purge excess agent from the diseased tissue prior to application of activating light. This is illustrated at several locations throughout the specification, including for example, the following passage (which immediately follows a section on application of the PDT agent (page 14, lns. 4-11)):

> "After a *brief accumulation period (generally not to exceed 30 minutes)*, the *excess agent is removed* from the tissue surface *by flushing* with liquid, such as with water or saline. Following this flushing, it is preferred that the residual agent associated with the diseased tissue be activated by illumination of the diseased site ...." (p. 14, lines 11-14, emphasis added)

This passage clearly supports limiting accumulation of agent to a period within 30 minutes following application.

Timing of subsequent light activation is described for example, in the following passage in the specification:

> "... PDT agent is applied to the disease site so as to cover, perfuse, or saturate the diseased tissue. *After a brief accumulation period ... excess agent is purged* or flushed from the disease site, and *a substantially uniform light field is applied* to the disease site in order *to activate the agent* associated with the diseased tissue." (p. 11, lines 13-17, emphasis added)

Thus, light is applied following this accumulation period, including immediately following removal of excess agent, as further illustrated by the following passage in the specification:

> "... the step of diagnosing can almost *immediately be followed by the steps of applying a PDT agent, purging excess agent and applying light* so that said method of diagnosis and treatment is done in a single procedure. If PDT agent uptake is used to diagnose or detect diseased tissue, the step of diagnosing can be *immediately followed by the step of applying activating light.*" (p. 12, lines 14-18, emphasis added)

Together, these passages support application of PDT agent, followed by an accumulation period not to exceed 30 minutes, and finally activation of residual agent immediately following such accumulation period.

Accordingly, Applicants are amending independent Claims 1, 31, 68 and 85 to more comprehensively define such details. The amended language of these claims is clearly supported by the specification as filed, such as for example, by those passages discussed above.

For instance, Claim 1 has been amended to recite:

> "...wherein said step of purging is performed within approximately 30 minutes of said step of applying said agent and further wherein said purging step is followed immediately by said activating step."

As shown in the above described passages, such language clearly is supported by the specification.

Similarly, Claim 31 has been amended to recite:

> "...allowing said PDT agent to accumulate in said diseased tissue for a period not to exceed 30 minutes; and
> applying a substantially uniform light field to said treatment zone ... said step of light application being performed immediately following said steps of PDT agent application and accumulation."

Such language is also supported by the disclosure of the above passages from the specification.

Similarly, Claim 68 has been amended to recite:

> "...allowing said PDT agent to accumulate in said diseased tissue for a period not to exceed 30 minutes; and
> applying minimally penetrating visible light to said diseased tissue ... wherein said step of light application is performed immediately following said steps of PDT agent application and accumulation."

Such language is also supported by the disclosure of the above passages from the specification.

Finally, Claim 85 has been amended to recite:

> "...allowing said Rose Bengal to accumulate in said diseased tissue for a period not to exceed 30 minutes; and
> applying a substantially uniform visible light to said diseased tissue ... wherein said step of light application is performed immediately following said steps of Rose Bengal application and accumulation."

Such language is also supported by the disclosure of the above passages from the specification.

For at least the above-stated reasons, Applicants respectfully submit that such amendments clarify the claimed methods of treatment of diseased tissue of the present invention and that the amendments to the claims are clearly supported by the application as filed. Therefore, it is respectfully requested that these amendments be entered and considered at this time.

Applicants will now address the Examiner's sole rejection in the Final Rejection.

II. Claim Rejections – 35 USC §112

In the Final Rejection, the Examiner rejects Claims 1-4, 11, 13-14, 16-17, 20-21, 23-28, 31, 35-39, 68-69, 71-72, 77, 79-80 and 82-86 under 35 U.S.C. §112, first paragraph, for alleged failure to comply with the written description requirement. This rejection is respectfully traversed.

In support of this rejection, the Examiner states that "the specification fails to disclose applying 'a substantially uniform light field'," and that "[t]he specification also fails to disclose applying light or activating the agent within approximately 30 minutes of the agent application step." While Applicants traverse this rejection, in order to advance the prosecution of this application, as described *supra*, the rejected independent claims have been amended. As shown above, the claims as amended are clearly supported by the present application as filed, and therefore, comply with the written description requirement, and it is respectfully requested that this rejection be withdrawn.

To further support Applicants' traversal of this rejection, each of the Examiner's specific issues pertinent to the Examiner's stated bases for rejection are discussed below in detail.

A. Substantially uniform light field

As mentioned above, the Examiner contends that the specification fails to disclose applying a substantially uniform light field. Applicants respectfully disagree as the specification of the present application as filed clearly teaches that it is desirable to apply "a substantially uniform light field" to diseased tissue under treatment in order to activate residual PDT agent contained therein. This is illustrated at several locations, including the following passage from the specification:

> "In general, the method of the present invention involves one or more of the following steps... a sufficient quantity of a topical or systemic formulation of a desired PDT agent is applied to the disease site so as to cover, perfuse, or saturate the diseased tissue. After a brief accumulation period to allow the agent to coat, perfuse, or otherwise

> become active within the diseased tissue, excess agent is purged or flushed from the disease site, and *a substantially uniform light field is applied to the disease site* in order to activate the agent associated with the diseased tissue." (p. 11, lines 8-17, emphasis added)

Salient examples illustrating how such a uniform light field is applied are provided at multiple locations throughout the specification, including the description of Figure 2(a) on p. 15, 3rd and 4th paragraphs (ln. 14 et seq.); the description of Figure 2(b) on p. 16, 3rd and 4th full paragraphs (ln. 11 et seq.); and the description of Figure 2(c) on p. 17, 3rd and 4th paragraphs (ln. 12 et seq.).

Accordingly, there is clear support in the specification for this claimed feature. Therefore, Applicants respectfully submit that the Examiner's rejection of Claims 1, 31, 68 and 85, and those claims dependent thereupon, based on alleged failure to comply with the written description requirement concerning use of applying "a substantially uniform light field" is incorrect and should be withdrawn.

B. Timing of Agent Application, Accumulation and Light Application

As explained in depth *supra*, while Applicants respectfully traverse the Examiner's basis for rejection concerning timing of agent application, accumulation and light application, in order to advance the prosecution of this application, independent Claims 1, 31, 68 and 85 have been amended to closely follow the wording of the disclosure in the present application. Such amendments overcome any basis for rejection of these claims or any claims dependent thereupon under §112.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

III. Information Disclosure Statement

Applicants filed an information disclosure statement (IDS) on April 27, 2006. As a RCE is being filed herewith, this IDS should be entered and considered at this time.

IV. Conclusion

For at least the above-stated reasons, it is respectfully submitted that the claims of the present application are in an acceptable and allowable form, and it is requested that the application be allowed.

If any further fee should be due for this amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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